

In the specification:

Please replace the paragraphs beginning at page 5, line 2, through to the paragraph ending at page 12, line 17, with the following amended paragraphs:

The implant 10 is a self-tapping and self drilling implant. Typically, when any type of device is said to be self-tapping, then the device must cut its way into the host site, in this case bone. Either the cut material must be compressed to allow the ~~erests~~ crest of the thread to pass through the bone, or bone material must be cut away permitting passage of the thread crest. In the case of a wood screw going into soft wood, the wood may be compressed on either side of the crest of the thread permitting the screw to advance into the wood and the crest of the thread to be received in the wood. Significant compression of this type is not acceptable in bone as this is likely to cause injury and in certain cases necrosis at the site of the thread crest. In order to not damage the surface of the bone which is immediately adjacent to the surface of the thread by compression, the cut material must be removed from the installation site. The cut material can be removed only by providing a path out of the installation site which does not generate significant compression of the host material. In the implant 10, the path for removal of bone cuttings is provided by the flute portions 26 and 28. In order to make that path as short as possible, the flute portions 26 and 28 extend substantially parallel to the axis 16. The flute portions 26 and 28 extend generally parallel to the axis 16 along the surface of the lead thread portion 20 and the intermediate thread portion 22. For reasons which will be discussed below, the flute portions 26 and 28 terminate at the end of the intermediate thread portion 22 and do not extend into the distal thread portion 24.

In order to install the implant 10, the surgical site may first be prepared for installation of the implant. The implant can be installed by directly engaging the soft tissue with the implant. In more typical situations, an incision will be made in the soft tissue. If desired a profiling drill may be used to create a dimple in the jaw bone at the desired location of the axis 16. This determines the location of the implant. The implant is then grasped in a tool to be discussed below at the head portion 14. Pressure in the

proximal direction is applied to the implant 10 and the implant 10 is rotated. The cutting edges 42 and 52 then begin to remove bone chips from the host bone at the installation site. As the cutting edges create bone chips, the bone chips are forced to flow in the distal direction along the flute portions 26 and 28. The ~~erests~~ crest of the thread portions 20, 22 and 24 are also sharp so as to provide a cutting edge to facilitate the installation of the implant. The implant is rotated and advances in the proximal direction as the ~~erests~~ crest of the threads thread engage engages the cut host bone. The procedure is continued until the implant has been installed to the desired depth.

As the implant advances proximally, bone chips can flow into the flute portions 26 and 28 and out of the flute portions 26 and 28 while those flute portions extend distally above the distal surface of the host bone. The distal end 30 of the flute portion 26 is visible in Figure 1. The second flute portion 28 also ends in a distal end which is located axially along the axis 16 adjacent to and diametrically opposite from the end 30.

As the implant nears its intended installation depth, the distal end 30 of the flute portion 26 will then be received in the host bone. As shown Figure 1, the distal thread portion 24 comprises a few additional revolutions of thread. As shown in Figure 1, this is approximately 3 revolutions. Thus, the flute portions 26 and 28 do not extend into the distal thread portion 24.

In order to facilitate the final flow of bone chips out of the flute portions 26 and 28 while the distal thread portion enters the host site, the surgeon can irrigate the site to remove additional bone chips as desired.

It is desirable that the fluted portions 26 and 28 remain filled with bone chips when the implant reaches the designed installation depth. The fact that the flute portions 26 and 28 do not extend into the distal thread portion facilitates ensuring that the flute portions remain filled with bone chips. Because the flute portions 26 and 28 represent a surface which is cut into what is otherwise a substantially cylindrical threaded surface of the implant 10, the surface of the flute portions 26 and 28 would be relatively distant from the host bone in the radial direction relative to axis 16. The distance between the surface of the flute portions 26, 28 and the host bone may lead to insufficient osseointegration, at least in the area adjacent to the surface of the flute portions 26 and

28. By ensuring that the flute portions 26 and 28 remain filled with the cut bone chips, this assists integration of the bone chips with the adjacent host bone leading to integration of the host bone with the surface of the fluted portions 26 and 28. To further assist in integration of host bone adjacent the surface of the flute portions 26 and 28, the surfaces of the flute portions 26 and 28 may be surface treated in any manner which enhances osseointegration. This may include roughening the surface by sand blasting or blasting with glass beads or the like, acid treatment or other surface modification techniques.

The surface of the implant 10 other than the surface of the flute portions 26 and 28 is relatively smooth. The surface along the thread from the crest to the root and any valley between adjacent ~~roots~~ revolutions must traverse along the host bone as the implant is threaded into the site. In order to minimize damage to the bone, the surface is relatively smooth so as to facilitate the sliding of the surface of the implant relative to the bone. However, once the implant is in place, it is intended that osseointegration occur. As explained above at the outset, much of the effect of the osseointegration is achieved by the helical thread on the exterior surface of the implant. However, micro osseointegration directly at the surface of the implant is also a factor in the stability of the implant and thus the surface is not intended to be so smooth that integration does not occur.

From reference to Figure 1, it can be appreciated how the implant cuts the aperture in the bone to accommodate the implant and the threaded portion of the implant. The cutting edges 42 and 52 are diagrammatically illustrated in Figure 1. From reference to Figure 2, it will be observed that the cutting edges 42 and 52 extend radially outwardly from the axis 16 to the circumference of the implant adjacent the first revolution of the thread of the lead thread portion 20. The ~~threads~~ thread of the lead thread portion 20, the intermediate thread portion 22 and the distal thread portion 24 comprise the usual crest and root. The lead thread portion 20 comprises three revolutions of the thread. A line indicated at 62 in Figure 1 joins the tips of the ~~crests~~ crest of the first three revolutions. This line is referred to herein and in the claims as a crest line. It will be observed that the crest line 62 is not parallel to the longitudinal axis

16. The crest line 62 extends radially outwardly in the distal direction relative to the axis 16, that is, the diameter described by the crest of the thread in the lead thread portion 20 increases in the distal direction from the tip portion. Thus as the implant is rotated, the crest of the thread in the lead portion cuts an increasing diameter until the crest of the thread in the intermediate thread portion 22 is accommodated. Thus, the crest widens the portion of the bone required to accommodate the crest of the thread over the course of the three revolutions of the lead portion of the thread.

From reference to Figure 2, it will be noted that the end of the cutting edge radially outwardly from the axis 16 is given as the points 43 and 53 of the cutting edges 42 and 52 respectively. Thus, the cutting edges 42 and 52 cut away bone to accommodate the ~~roots~~ root of the thread out to a diameter defined by the points 43 and 53. This point is shown in Figure 1 as the point 43. The line 45 illustrated in Figure 1 is a line parallel to the axis 16 of the implant passing through the outwardly extremity 43 of the cutting edge 42 ~~and is referred to herein~~. The line 47 in Figure 1, is a line drawn through the ~~roots~~ root of a the thread in the intermediate portion 22 and the distal portion 24. The line 45 is displaced from the axis 16 by a distance referred to herein as the cutting edge distance. The line 47 is referred to herein as the root line and the distance of the root line from the axis 16 is referred to as the root distance. The distance between the lines 47 and 45 is shown by the arrow 49.

The distance 49 as illustrated in Figure 1, illustrates the amount of compression that will be applied to the surface of the bone as the implant passes proximally into the bone. The bone is cut away by the cutting edges 42 and 52 leaving a cylindrical hole. Some further cutting action takes place in the bone by the ~~crests~~ crest of the thread of the lead portion. As the ~~crests~~ crest of the thread of the lead portion pass any particular point in the bone, the bone is then compressed a total amount as shown by the distance 49.

The angle of the crest line 62, relative to the axis, establishes a rate of compression, that is, the greater the angle between the ~~lines~~ crest line 62 and the axis 16, the greater will be the speed of compression for a given rotational speed of the

implant 12. The implant may be designed to give any desired rate of compression by including fewer or greater number of revolutions in the lead thread portion.

The distance 49 between the lines 45 and 47 establishes the amount of compression the surface of the bone will be subjected to. That dimension can be altered by altering the radial length of the cutting edges 42 and 52. It will be appreciated by those skilled in this art, that it is desirable to have some compression so as to facilitate osseointegration with the underlying bone. However, too much compression can cause problems including necrosis of the bone cells being compressed. Where an implant is being installed in a less dense bone which is more forgiving, the distance 49 may be larger, perhaps up to as large as 1/3 of the radial distance between the axis 16 and the line 47, that is, the root distance. However, in more dense bone, the amount of compression that may be satisfactory may be much less, perhaps as little as 5%. As those familiar with this area will be well aware, the jaw bone in a human is composed of areas of quite different density. The back portion of the upper jaw is much softer than the front portion of the lower jaw. In relatively softer or less dense bone, a higher permissible compression amount and a higher permissible rate may be acceptable without damaging the bone. In dense bone however, it is likely that there will be a much lower permissible compression amount and a lower permissible compression rate.

The intermediate thread portion 22 commences, as shown in Figure 1, with the crest of the forth revolution of the thread from the tip portion 18. The line 64 referred to herein as the intermediate portion crest line, joins the tips of the ~~crests~~ crest of the thread in the intermediate thread portion 22 and in the distal threaded portion 24. The intermediate portion crest line 64 is parallel to the axis 16. This means that there is no additional cutting required to accommodate the ~~crests~~ crest of the thread in the intermediate and distal thread portions to allow passage of the intermediate thread portion 22 or the distal thread portion 24 in the host bone. Similarly the root line 47 joining the ~~roots~~ root of the ~~threads~~ thread in the intermediate thread portion 22 and the distal thread portion 24 is also parallel to the axis 16. These two factors mean that there is no further cutting of the bone at a particular location in the bone once the tip portion 18 and the lead thread portion 20 have passed that particular location.

Osseointegration occurs as the host bone grows around and incorporates the surface of the implant 10. The surface of the entire tip portion 18, the lead thread portion 20, the intermediate thread portion 22 and the distal thread portion 24 will all be in intimate contact with the host bone. As the self tapping implant passes into the bone, there is no excess space or clearance between the implant and the host bone. The only portion of the implant which is not in close contact with the host bone is that portion represented by the surface of the flute portions 26 and 28. For this reason, the circumferential width of the flute portions 26 and 28 should be minimized as much as possible, while providing sufficient space to allow the bone chips created during installation of the implant, to flow along the flute portion and so be removed from the site of the cutting action. As stated above, the passageway defined by the surface of the flute portions 26 and 28 and the surrounding host bone will be filled with bone cuttings generated by the cutting edges. This passageway will remain filled when the implant has been passed in the proximal direction into the bone to the desired depth. Because the flute portions 26 and 28 do not extend into the distal thread portion 24, then there is circumferential contact all the way around the surface of the implant 10 adjacent the distal thread portion 24. The top three revolutions of the thread, that is the thread in the distal thread portion 24, will be in contact with the superior cortex to provide good engagement at the top of the implant. Most stabilization of the implant occurs in the superior cortex and accordingly, it is desirable to have maximum surface area available for integration. In part, this can be achieved by having the flutes 26 and 28 not extend any further distally than necessary for bone chip removal.

The head portion 14 of the implant 10 comprises a generally cylindrical outer surface 70. The diameter of the generally cylindrical surface 70 may be substantially equal to the diameter of the root of the thread in the intermediate and distal threaded portions. The distal end of the cylindrical surface 70 of the head 14 merges with an outwardly flaring tapered surface 72.

In Figure 1, the head portion 14 is shown in partial section. The head portion 14 comprises an internal bore 80. The internal bore 80 extends generally co-axially with the axis 16. A proximal portion of the bore 80 may be threaded as indicated at 82. The

internal thread indicated at 82 of the bore 80 provides a structure for fixing various other structures to the implant 10. During the initial healing stage, a healing cap is used to close the distal end of the bore 80. When the implant is used for the support of a prosthesis, the prosthesis may be attached to an abutment. The abutment will have a thread which is complimentary to the internal thread 82 of the bore 80.

The proximal end of the bore 80 is shown at 84. From Figure 1 it will be noted that, preferably the distal end 30 of the flute 26 is spaced in the proximal direction from the proximal end 84 of the bore 80. The radial depth of the flute 26 might otherwise encroach upon the wall thickness between the bore 80 and the root of the distal thread portion 24. This in turn might require a bore with a smaller diameter which is not desirable. The radial depth of the flutes 26 and 28 is greatest at the proximal end of the flute and the flute radial depth tapers to zero adjacent the distal end of the flute.

The implant 10 may be made from any material which is suitable for integration into the body. Typically, this may be metals such as titanium or titanium alloys. However, other materials may be used including stainless steel.

In order to install the implant, the site is prepared for installation. A profiling drill is used to make a small dimple in the bone. The dimple is located at the desired location for the axis 16 of the implant. The implant may then be gripped by means of a standard dental tool which grasps the head portion 14 of the implant 10. The head portion 14 of the implant 10 is grasped to prevent any relative rotation between the installation tool and the implant 10. Pressure is then applied to the implant in the proximal direction and the tool is used to rotate the implant. When the implant has been positioned to the desired depth, the tool is removed from the head portion of the implant. Thereafter a healing cap is inserted into the head portion of the implant and the surgical site closed temporarily to permit integration of the implant into the host bone. Typically, integration may take 4 to 6 months. Upon integration of the implant, the site may be opened at the distal end and a prosthesis attached to the implant by means of the ~~threads~~ thread 82 in the internal bore 80.

While the invention has been discussed in the context of the preferred embodiment, it will be apparent that various modifications may be made.